Information Summary and Recommendations

ASSESSMENT OF THE QUALITY OF LABORATORY TESTING

January 1994

For more information on
this report contact:

Office of Laboratory Quality Assurance
1610 N.E. 150th Street
Seattle, WA 98155-9701

(206) 361-2806
SCAN 245-2806
FAX 361-2813

Bruce A. Miyahara
Secretary of Health

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Executive Summary

In 1991, legislation was proposed to license clinical laboratory science practitioners. Because there was not sufficient data presented in the sunrise review to support licensure, the Department of Health recommended registration only. Prior to making its recommendation to the legislature, the Board of Health requested a study of the Medical Test Site licensure program to determine if the facility licensure program is adequate to assure the quality of clinical laboratory testing.

In Part I of the study, findings were based on data gathered from the initial on-site inspections of 194 previously unregulated medical test sites; these inspections were conducted between February 1991 and May 1992. The data showed a correlation between quality of performance and level of training of personnel. In Part II, 101 of these sites were re-evaluated after a second inspection. The second cycle of inspections occurred between December 1992 and September 1993. There were significant improvements in quality of performance for all labs, but there was no correlation between improvement and the type of personnel.

Although the data from the Part II of the study may not indicate a need for personnel licensure, the professional judgement of staff that participated in the study is that the level of personnel training is critical to the quality of testing.

This study evaluated less than 200 of the approximately 900 labs that require on-site inspections. Because of the limited scope and insufficient evidence in the study to justify personnel licensure, the Department of Health does not consider that licensure is necessary at this time. The medical test site licensure regulations, which now includes personnel qualifications, have been shown to be effective in improving the quality of clinical laboratory testing. However, if the medical test site program is repealed, a personnel licensure program might be necessary to assure that testing personnel are appropriately educated and trained. A bill to repeal the program has been introduced in this legislative session. Also, if the federal personnel requirements, which the State has adopted, become less stringent, the Department would then reassess the need for personnel licensure.

Summary of Major Findings

PART I: INITIAL ON-SITE INSPECTIONS OF 194 LABORATORIES

- **URBAN vs RURAL LABORATORIES**
  No significant differences in number of deficiencies

- **PERSONNEL**
  Personnel without lab training had, on average, more deficiencies (4.5) than trained personnel (3.0)

- **DISCONTINUED TESTING**
  Personnel without lab training discontinued testing at a higher rate than trained personnel: 48% vs 18%

- **PARTICIPATION IN PROFICIENCY TESTING (PT)**
  77% of labs not participating in PT had personnel without lab training

PART II: 101 LABS REINSPECTED

- **NUMBER OF DEFICIENCIES**
  65% of labs showed a decrease in number of deficiencies

- **REPEAT DEFICIENCIES**
  15% of all labs

- **PERSONNEL**
  6% of labs hired trained personnel to replace personnel without training

- **DISCONTINUED TESTING**
  23% of all labs discontinued at least 1 test, with no significant difference between personnel types

- **PARTICIPATION IN PROFICIENCY TESTING (PT)**
  Overall improvement for all labs. Labs with PT failures had higher number of serious deficiencies and a higher rate of repeat deficiencies

BACKGROUND

In 1991, the Washington State Society for Medical Technology introduced SB 5907 to license clinical laboratory science practitioners. A Sunrise Review was conducted.

In the summary of evidence and findings, the Department's Sunrise Review Committee concluded that the applicant group demonstrated that the lack of regulation of laboratory testing increases the risk of poor quality outcomes. However, the information provided did not show that the recently established regulatory programs under the authority of Washington State (Chapter 70.42 RCW, Medical Test Site Licensure) and the federal Clinical Laboratories Improvement Amendments (CLIA '88) were inadequate to address the problems cited.

The Department recommended against establishing personnel licensing requirements, stating that such requirements would be premature due to the lack of data. The Board of Health requested that the Office of Laboratory Quality Assurance prepare a report by fall of 1993 to assess the effects of the Medical Test Site Licensure program.

THE MEDICAL TEST SITE LICENSURE LAW

The Washington State Medical Test Site Licensure law (RCW 70.42) has undergone several revisions since its implementation in November 1990. When on-site inspections of laboratories began in February 1991, there were no personnel requirements other than for the laboratory director. There were 23 laboratory tests recognized as "waived" from the regulations.

Due to an attempted repeal of the Medical Test Site Licensure law in October 1991, an emergency rule went into effect which added three additional laboratory tests to the waived list: direct strep antigen, whole blood glucose by devices FDA-approved for home use and urine colony count. Many physician office laboratories became waived as a result of this WAC revision.

The federal Clinical Laboratory Improvement Amendment of 1988 (CLIA) went into effect September, 1992. Washington State applied for an exemption, as provided under the CLIA regulations. Significant WAC revisions were made in order for the state's program to be recognized as "equivalent" to CLIA requirements. Included in the necessary revisions was the adoption of CLIA personnel standards, test complexity categorizations and the limited list of waived laboratory tests. These revisions were finalized in the fall of 1993.

In October 1993, the state of Washington was distinguished as being the first state to be granted an exemption from the CLIA regulations.

OTHER STUDIES

There have been numerous studies which indicate differences in test performance by formally trained and non-formally trained laboratory testing personnel and which demonstrate the effects of regulations on laboratory testing.

A study by Lamotte[1], based on seven years experience with previous federal laboratory regulations (CLIA '67), found that key indicators of a laboratory's reliability were related to personnel qualifications and competence and to the adequacy of the internal quality control program. Laboratories with the least number of quality control errors were those with the highest percentage of medical technologists in the workforce. Similarly, in a study by Lunz, Castleberry, James and Stahl[2], accuracy scores on proficiency testing were higher when there was a higher percentage of medical technologists.

Studies by Grayson[3], which evaluated proficiency testing data and the results of a questionnaire from regulated and unregulated laboratories in California, concluded that there was suboptimal testing performed in unregulated labs and significant differences when laboratories were subjected to conspicuous regulatory activities. To further support this concept, a study by Bloch, Cembrowski, and Lembesis[4] concluded that proficiency testing alone has too little influence on laboratory performance. Increased regulation and consultation services were recommended by these authors.

Studies by Nanji, Poon, Hinberg[5] where desk top analyzers were used by technologists and non-technical personnel, suggested that while modern instrumentation is capable of excellent accuracy and precision, there are additional responsibilities for non-technical personnel to understand the concepts of precision, accuracy, bias, quality control, specimen handling and processing, documentation and instrument maintenance.

STUDY OBJECTIVES

To assess the quality of laboratory testing in previously unregulated laboratories and the effects of the Washington State Medical Test Site Licensure program, a two part study was conducted. In Part I, data were gathered from the initial on-site inspections of 194 previously unregulated laboratories. Conclusions were drawn regarding the differences in numbers and types of deficiencies and proficiency testing participation among testing personnel categories. In Part II, 101 of these laboratories were re-evaluated after a second inspection to determine the effects of the first two-year cycle of the regulatory program.

METHODOLOGY

The following criteria were used to select laboratories for this study:

- Not previously subjected to any laboratory regulations. Excluded were hospital, independent and interstate labs, which were previously regulated under federal Medicare rules.
- Initial inspection was completed soon after implementation of the Washington State Medical Test Site Licensure law.
- Equal representation from all regions in the state.
- Random selection of the first 194 laboratories based on the date of the initial inspection and meeting the above criteria.

DATA EXTRACTION

After the completion of the initial inspection, data were extracted with respect to geographic location, laboratory specialties, personnel categories, deficiencies, proficiency testing participation and discontinued testing.

Geographic location Laboratories were designated urban or rural, by the use of standardized population density charts.

Specialties The number of laboratory specialties (groups of similar laboratory tests) were recorded for each laboratory. Recognized specialties were: Chemistry, Hematology, Bacteriology, Diagnostic Immunology, Cytology, Immunohematology, Pathology and Histocompatibility.

Personnel Categories Laboratories were categorized according to the following designations if there was at least one person at that level performing tests:

- MT/MLT: medical technologist (MT) or medical laboratory technician (MLT)
- RN/ARNP: registered nurse (RN) or advanced registered nurse practitioner (ARNP) but no MT/MLT
- OTHER: no testing personnel in either of the first two categories. This category included certified medical assistants (CMA), medical assistants (MA), licensed practical nurses (LPN), x-ray technicians, on-the-job trained (OJT), military trained, and respiratory therapists (RT).

These personnel categories are based on similarities in the training and experience of the personnel. MT and MLT personnel have at minimum an associate degree in a formal laboratory training program. RN/ARNP personnel have at minimum an associate degree in biologic sciences, although they do not have formal laboratory training. The OTHER category included all other health care disciplines, which were not further delineated since there were too few in each group for statistical significance.

Deficiencies were evaluated as follows:

- **Total Deficiencies** - The total number of deficiencies cited in a facility during the on-site inspection.

- **Serious Deficiencies** - The number of deficiencies of the total which were determined to be serious, according to established criteria (Figure 1).

- **Total Deficiencies/Number of Specialties** - Since the data showed that the number of total deficiencies increased with the number of laboratory specialties, the number of total deficiencies divided by the number of laboratory specialties for each facility was calculated. This provided a means of comparing data among laboratories with different numbers of laboratory specialties.

Proficiency Testing Participation All laboratories were required to enroll in a proficiency testing program to cover tests in each laboratory specialty performed. Categories of participation were defined as follows:

- **Enrolled** - Laboratories which were fully enrolled in proficiency testing for tests in each specialty performed.

- **Not Enrolled or Under Enrolled** - Laboratories which were not enrolled in proficiency testing or were partially enrolled but did not cover testing in each specialty as required.

- **No Copies** - Laboratories which were enrolled in proficiency testing but had not assured that copies of results were sent to our department for monitoring as required.

Proficiency Testing Performance was determined for each laboratory by the numbers of cautionary letters issued by our office for consecutive proficiency testing failures.

Warning letters were issued to laboratories when two consecutive failures occurred on the same test or specialty. Laboratories were required to take corrective action and to submit a written plan of correction to our office in order to continue the testing.

Discontinue letters were issued to laboratories when three consecutive failures occurred on the same test or specialty. Laboratories were required to discontinue analyzing patient specimens for the test in question.

DATA ANALYSIS

Data were analyzed using RAOSOFT "Survey" ™ software program. Test of significance were made using the classic t-test, at 95% confidence limits.

FINDINGS - PART I

Demographics

Of the laboratories that were inspected between February 1991 and May 1992, 194 laboratories were evaluated with nearly equal representation from all geographical regions. Sixty-six percent were from urban areas and 34% were from rural areas. An average of two specialties were performed per laboratory with a range of one to five specialties.

Laboratories were categorized according to the testing personnel: 91 (47%) designated as MT/MLT; 43 (22%) as RN/ARNP; and 60 (31%) as OTHER. Laboratories with the designation of OTHER, had personnel as follows: 36 CMA/MA, 9 LPN, 9 OJT, 3 Military, 2 MD and 1 X-Ray.

A total of 738 deficiencies were written in the 194 laboratories, with 40% being judged as "serious" deficiencies. An average of 3.8 total deficiencies were written per laboratory with a range of 0-14. Serious deficiencies averaged 1.5 per laboratory, with a range of 0-9.

There were no significant differences in the mean number of deficiencies written in urban versus rural laboratories.
(Figure 2).

Personnel without formal laboratory training had significantly higher numbers of deficiencies than those with formal laboratory training. The mean of total deficiencies for non-MT/MLT laboratories exceeded those of MT/MLT laboratories by a factor of 1.5. The mean of total deficiencies/specialty for non-MT/MLT laboratories exceeded those of MT/MLT laboratories by a factor of 2.5 (Figures 2, 3 and 4).

Of the 30 laboratories with total deficiencies/specialty greater than twice the all laboratory mean, 87% were non-MT/MLT laboratories. In contrast, of the 42 laboratories with no deficiencies written on initial inspection, 83% were MT/MLT laboratories (Figure 5).

Laboratories which employed personnel without formal laboratory training discontinued testing at a significantly higher rate than those which employed personnel with formal laboratory training. Sixty-four of the total 194 laboratories (33%) dropped one or more tests within the first year of the program. Eighteen percent of laboratories designated MT/MLT dropped some type of testing compared to 42% of laboratories designated as OTHER and 54% of laboratories designated as RN/ARNP. Twelve percent of RN/ARNP laboratories and 13% of OTHER laboratories chose to drop to waived status as opposed to 2% of laboratories with MT/MLT personnel. More RN/ARNP and OTHER laboratories dropped Bacteriology testing (14% and 12% respectively) than did MT/MLT laboratories (3%) (Figure 6).

The numbers of deficiencies were significantly higher in laboratories which discontinued testing (Figure 7).

There were no significant differences between personnel categories with regard to the patterns of deficiencies written under the major areas of proficiency testing, personnel, recordkeeping, quality assurance and quality control. Deficiencies written were as follows: 43% quality control, 24% recordkeeping, 19% quality assurance, 8% personnel, 6% proficiency testing.

Enrollment in proficiency testing was significantly lower in laboratories with personnel without formal laboratory training. Of the 194 laboratories, 128 (66%) were fully enrolled in proficiency testing, 51 (26%) were not enrolled or were under-enrolled and 15 (8%) had not assured that copies of results were sent to our department for review. Of the laboratories which were not enrolled or under-enrolled, 77% were non-MT/MLT laboratories (Figure 8).

The numbers of deficiencies were significantly higher in laboratories which were under enrolled or were not enrolled in proficiency testing (Figure 8).

Due to the less than optimal enrollment overall, and the disproportionate enrollment by different personnel categories, no attempt was made to correlate proficiency testing performance with numbers of deficiencies or personnel types.

Overall, where we received some proficiency testing data, 66% of laboratories received no cautionary letters, 28% received at least one "warning" letter and 5% received at least one "discontinue" letter, as of September 1992.

FINDINGS - PART II

Of the laboratories inspected in Part I, 101 were re-inspected between December 1992 and September 1993. A total of 202 deficiencies were written, with 16% being judged as serious.

There was a significant decrease in the number of deficiencies from the first to the second inspection. The mean of total deficiencies for all laboratories decreased by 47%. Sixty-five percent of laboratories showed a decrease in their number of total deficiencies from the initial inspection. The mean of serious deficiencies decreased by 78%. Fifty-six percent of laboratories showed a decrease in their previous number of serious deficiencies (Figures 9 and 10).

Fifteen percent of laboratories had uncorrected deficiencies from the first inspection.

Six percent of laboratories changed testing personnel from non-MT/MLT on the first inspection to MT/MLT on the second inspection.

During the second year of the program, 23% of the 101 laboratories discontinued at least one test, with Chemistry testing dropped most frequently, followed by Bacteriology testing. There were no significant differences in the rates of discontinued testing between personnel categories.

Enrollment in proficiency testing improved for all categories of personnel. Laboratories which were fully enrolled in proficiency testing increased to 91%.

Laboratories with proficiency testing failures had a significantly higher number of serious deficiencies and had a higher rate of repeat deficiencies than laboratories which did not have any failures.

The frequency of proficiency testing failures remained relatively the same during the second year of the program. Twenty-seven percent of laboratories received at least one warning letter, and three percent received at least one discontinue letter for consecutive proficiency testing failures.

SUMMARY OF FINDINGS

Significant differences between testing personnel categories were found on initial inspection with respect to the numbers of deficiencies, the rates of discontinued testing and proficiency testing participation.

By the second inspection, laboratories which remained in the program showed significant improvements in the number of deficiencies and in proficiency testing participation. Rates of uncorrected deficiencies were low.

Participation in proficiency testing was an indicator for better performance, as demonstrated by the correlation of lower numbers of deficiencies in laboratories which were fully enrolled in proficiency testing. Laboratories which utilize this external means of assessing test accuracy have additional opportunities to recognize and correct problems.

Our regulatory program and the process for assessment can only address **indicators** of the quality of laboratory testing. True patient outcomes are not readily accessible through a regulatory oversight program such as ours. Nonetheless, it is evident that a program which includes on-site inspections, proficiency testing monitoring and a readily accessible staff for consultation and training has a significant impact on the improvement of quality of laboratory testing in all settings.

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2. Lunz, M.W., Castleberry B.M., James, K., Stahl, J. The Impact of the Quality of Laboratory Staff on the Accuracy of Laboratory Results. JAMA 1987 July; 258(3):p361-63.

3. Grayson, R.T. Effects of Regulatory Controls on the Accuracy of Clinical Laboratory Tests. J Med Tech 1984; 1:p632-637.

4. Bloch, Cembrowski, Lembesis. Longitudinal Study of Error Prevalence in Pennsylvania Physician Office Laboratories. JAMA 1988.

5. Nanji, A.A., Poon, R., Hinberg, I. Quality of Laboratory Testing Results Obtained by Non-Technical Personnel in a Decentralized Setting. AJCP 1988;89:797-801.

ASSESSMENT OF THE QUALITY OF LABORATORY TESTING

Appendices
Figures 1-10

Figure 1 CRITERIA FOR THE DESIGNATION OF DEFICIENCIES AS NON-SERIOUS AND SERIOUS

NON-SERIOUS

Systems for quality control and quality assurance are in place but there are occasional omissions in record keeping. Procedures and policies are incompletely written, yet the staff demonstrate a good understanding of procedures and adequately carry out protocols. Quality control and proficiency testing data support that the testing is being performed correctly.

SERIOUS

A serious deficiency is one which could lead to an incorrect diagnosis, inappropriate treatment or the need for additional, unnecessary diagnostic procedures.

Examples of actual deficiencies determined to be serious:

- No follow up on proficiency testing errors
- Patient results reported when quality control results were unacceptable
- Use of invalid procedures which did not meet recognized standards of laboratory practice
- Medically improbable patient values reported with no evidence of follow up
- The use of expired laboratory reagents for patient testing
- Multiple unlabelled patient specimens in the laboratory work area

Figure 2 DEFICIENCIES WRITTEN ON INITIAL INSPECTION

		Total Defic	Serious Defic	Total Defic per Specialty
	N	Mean	Mean	Mean
All Labs	194	3.8	1.5	2.0
Urban	129	3.7	1.3	2.0
Rural	65	4.0	1.9	2.2
MT/MLT	91	3.0	1.1	1.1
Non-MT/MLT	103	4.5	1.8	2.8
RN/ARNP	43	4.9	2.0	3.2
OTHER	60	4.3	1.7	2.6

Figure 3 DEFICIENCIES IN LABS GROUPED ACCORDING TO THE NUMBER OF SPECIALTIES PERFORMED

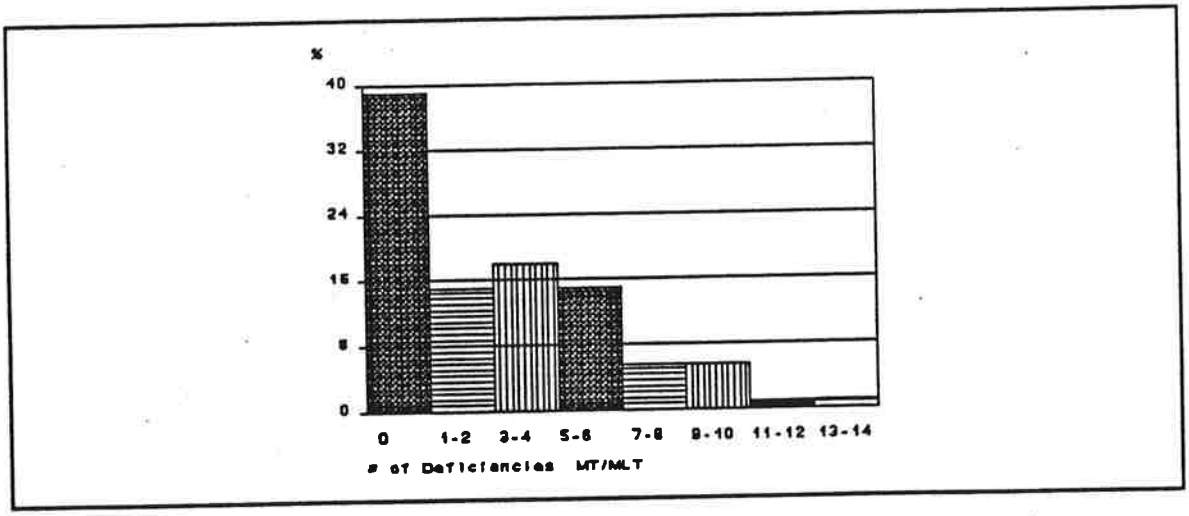
Total Deficiencies:

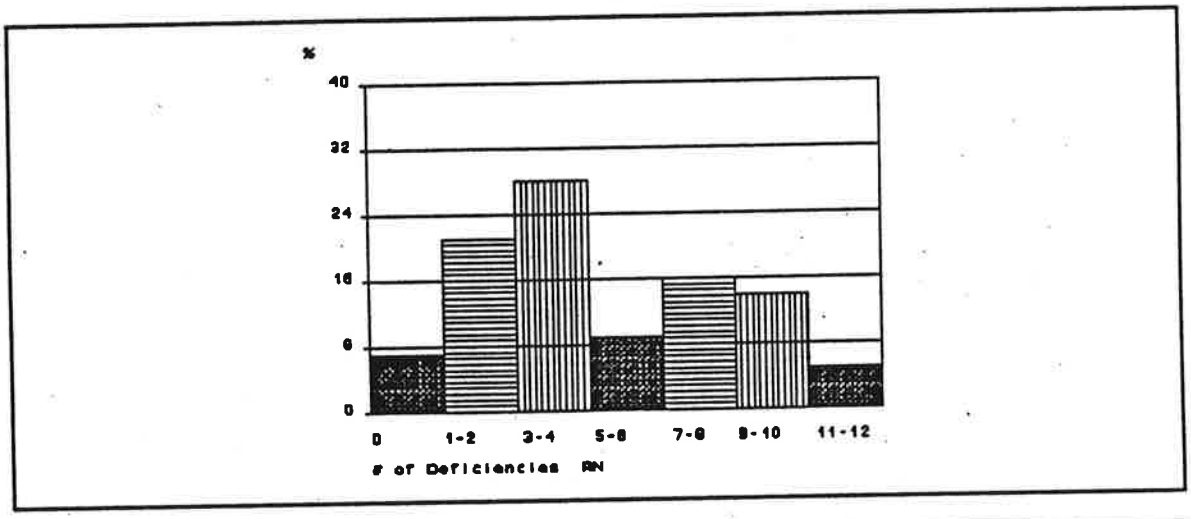
	All Labs		MT Labs		RN Labs		OTHER Labs	
Number of Specialties	N	Mean	N	Mean	N	Mean	N	Mean
one	59	2.9	16	0.8	21	3.7	22	3.6
two	70	3.6	30	1.8	16	5.6	24	4.6
three	52	4.4	34	3.9	5	6.8	13	4.5
four	12	6.3	10	5.8	1	9.0	1	8.0
five	1	12.0	1	12.0	0	-	0	-

Serious Deficiencies:

	All Labs		MT Labs		RN Labs		OTHER Labs	
Number of Specialties	N	Mean	N	Mean	N	Mean	N	Mean
one	59	1.2	16	0.3	21	1.8	22	1.3
two	70	1.3	30	0.8	16	1.8	24	1.7
three	52	1.8	34	1.5	5	2.6	13	2.2
four	12	2.4	10	1.8	1	5.0	1	6.0
five	1	9.0	1	9.0	0	-	0	-

Figure 4
PART I - NUMBER OF TOTAL DEFICIENCIES BY PERSONNEL TYPES





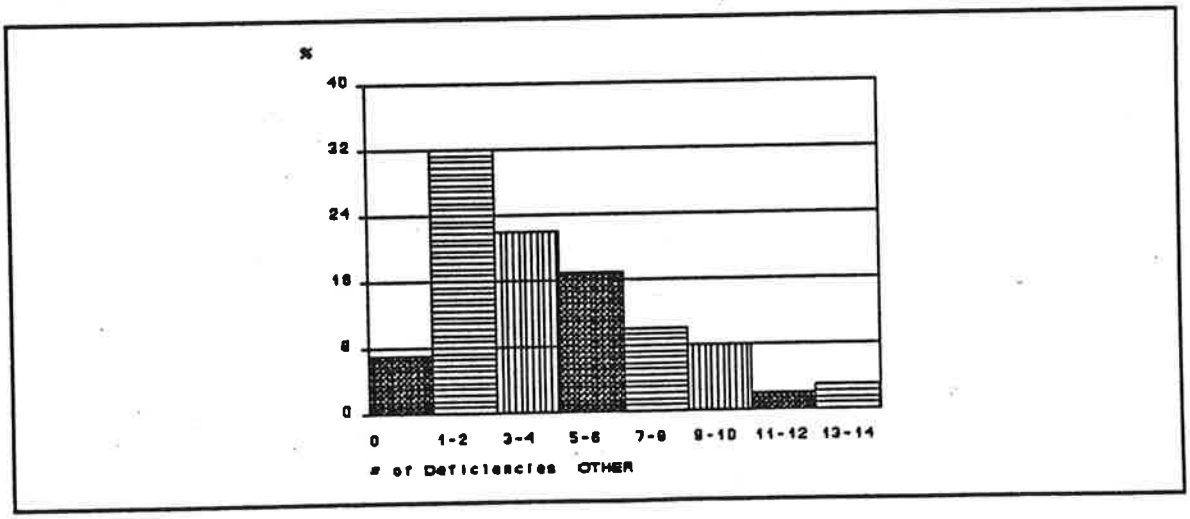
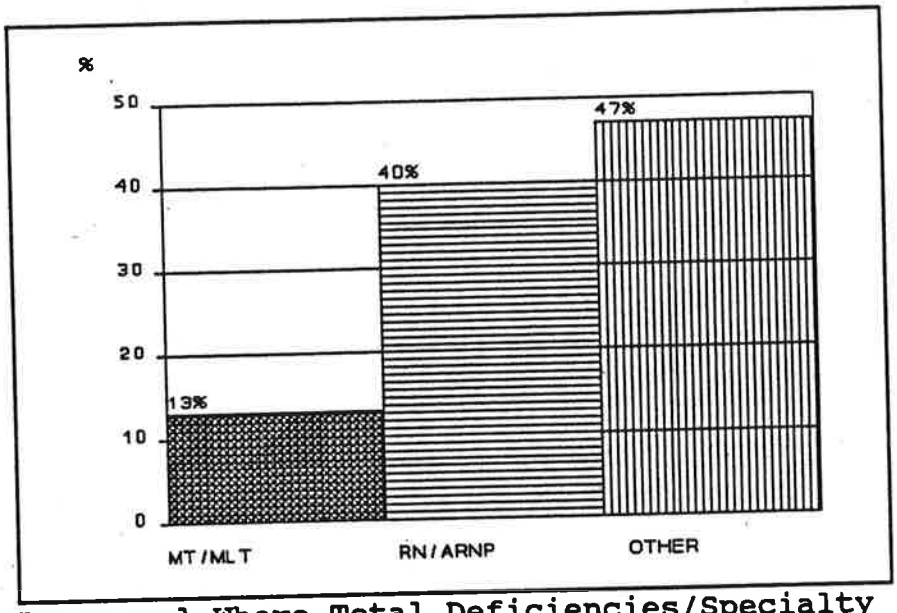
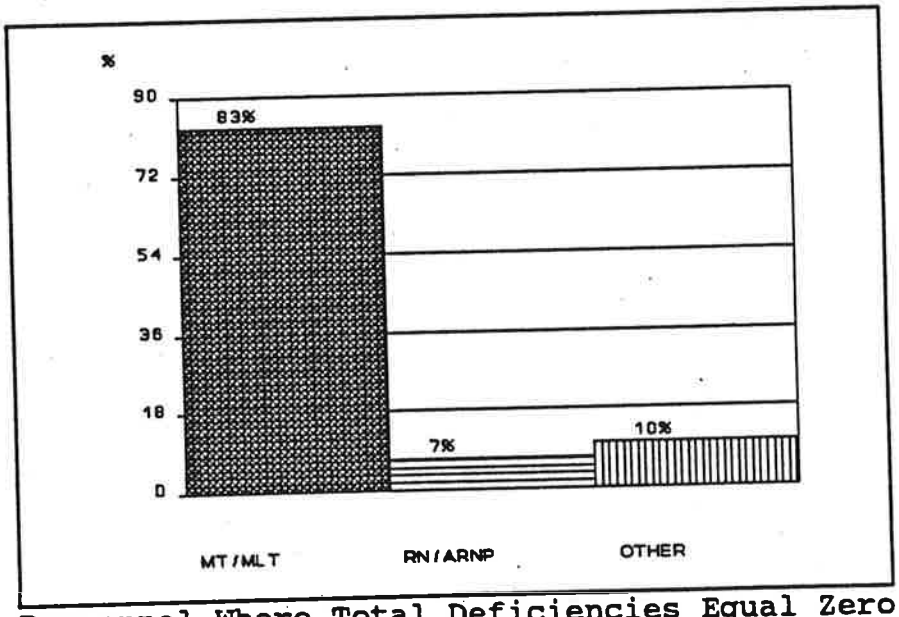


Figure 5



Personnel Where Total Deficiencies/Specialty Exceed Twice the Mean (N = 30 Labs)



Personnel Where Total Deficiencies Equal Zero (N = 42 Labs)

Figure 6 DISCONTINUED TESTING

	% All Labs	MT/MLT	RN/ARNP	OTHER
Discontinued Testing to Become Waived	7.7	2.2	11.6	13.3
Became Waived Due to WAC Revision	3.6	0.0	7.0	6.7
Discontinued:				
Bacteriology Test(s)	8.3	3.3	14.0	11.7
Hematology Tests(s)	1.6	1.1	2.3	1.7
Chemistry Tests(s)	5.7	5.5	7.0	5.0
Tests from Multiple Specialties	4.6	4.4	9.3	1.7
Out of Business/Moved	1.6	1.1	2.3	1.7
Did Not Discontinue Tests	67.0	82.4	46.5	58.3

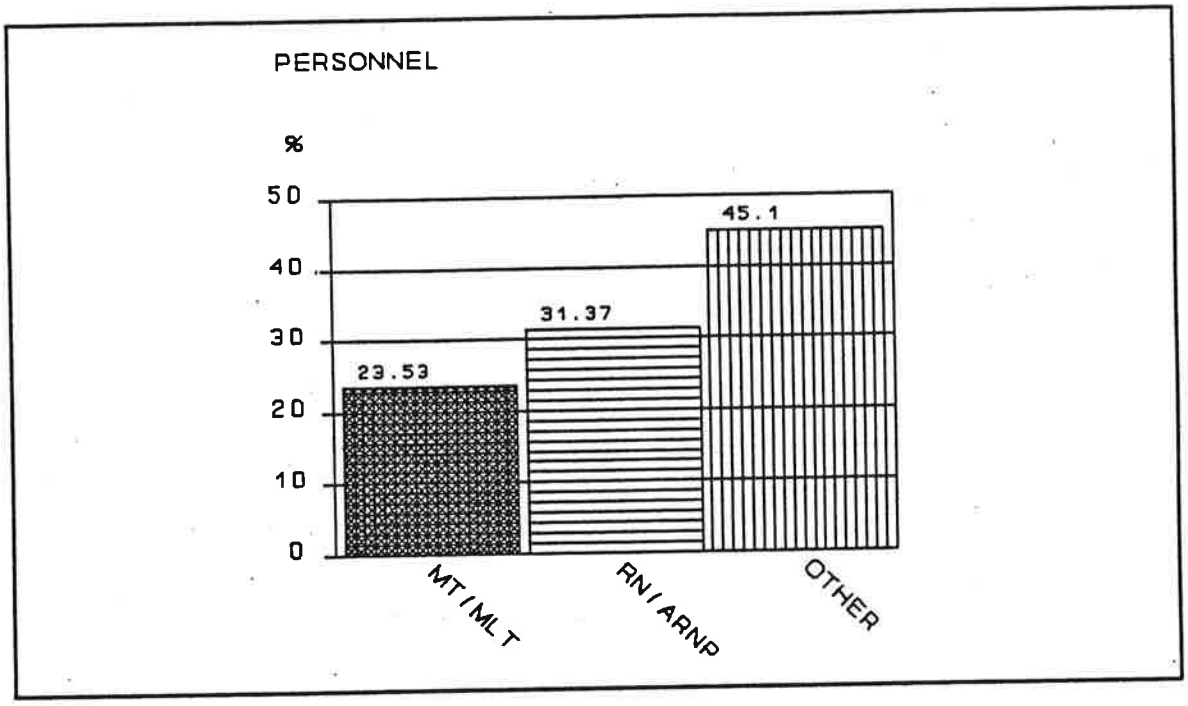
Figure 7 DEFICIENCIES IN LABS WHICH DISCONTINUED TESTING

	N	Total Defic Mean	Serious Defic Mean	Total Defic per Specialty Mean
Labs Which Discontinued Testing	54	5.4	2.4	2.9
Labs Which Did Not Discontinue Testing *	140	3.2	1.2	1.7
All Labs	194	3.8	1.5	2.0

* Includes labs which changed to waived due to WAC revision and labs which went out of business or moved.

Figure 8

PERSONNEL TYPES WHO WERE NOT ENROLLED OR WERE UNDER ENROLLED IN PROFICIENCY TESTING (N=51 Labs)



DEFICIENCIES IN LABS WHICH WERE NOT ENROLLED, UNDER-ENROLLED OR HAD NO COPIES SENT FOR PROFICIENCY TESTING

		Total Defs	Serious Defs	Tot Def/Spec
	N	Mean	Mean	Mean
Labs not enrolled, under enrolled or no copies sent	66	5.3	2.2	2.8
Labs fully enrolled	128	3.0	1.1	1.6
All Laboratories	194	3.8	1.5	2.0

Figure 9 COMPARISON OF FINDINGS: FIRST AND SECOND INSPECTIONS

	First Inspection	Second Inspection
Number of labs inspected	194	101
Total deficiencies written	738	202
% of total judged as serious	40%	16%
Mean of total defs per lab	3.8	2.0
Range of total deficiencies	0-14	0-9
% of labs with > 5 total defs	35%	15%
% of labs with > 10 total defs	4%	0%
Mean of serious defs per lab	1.5	0.3
Range of serious deficiencies	0-9	0-4
% of labs with > 3 serious defs	22%	4%
% of labs with > 5 serious defs	8%	0%
% of labs fully enrolled in proficiency testing	74%	91%

Figure 10 COMPARISON OF DEFICIENCIES
FIRST AND SECOND INSPECTIONS

		N	Total Deficiency Mean	Serious Deficiency Mean
1st Inspection		194	3.8	1.5
2nd Inspection		101	2.0	0.3
BY PERSONNEL TYPES				
MT/MLT	1st Inspection	91	3.0	1.1
	2nd Inspection	61	2.1	0.3
RN/ARNP	1st Inspection	43	4.9	2.0
	2nd Inspection	14	1.6	0.4
OTHER	1st Inspection	60	4.3	1.7
	2nd Inspection	26	2.0	0.4